



Notified Body No. 1023
INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a.s.
trida Tomase Bati 299, Louky, 763 02 Zlin, Czech Republic

EU Quality Management System Certificate No. 25 0383 QR/NB

Quality management system of the company

Astron Dental Corporation

815 Oakwood Rd. Unit G, Lake Zurich, Illinois, 60047, USA

SRN: US-MF-000034006

is certified in accordance with the requirements of

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medical devices, Annex IX, Chapters I and III

for the following device-range:

Occlusal Splint Appliance Material

Notified Body No. 1023 declares that it has assessed the quality management system of the above manufacturer in accordance with Annex IX, Chapters I and III of Regulation (EU) 2017/745. The quality management system put in place by the manufacturer for the design, manufacture and final inspection of the products concerned complies with the requirements of Regulation (EU) 2017/745 and is subject to regular surveillance audits. A detailed description of the system elements, requirements and measures adopted by the manufacturer is provided in the final report No. 803602921/2025, which is issued together with the present certificate.

Valid from: 2025-09-26

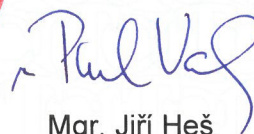
Valid until: 2030-09-25

Previous EU certificate No.: -

Previous EU certificate issue date: -



Date of issue: 2025-09-26


Mgr. Jiří Heš

Representative of Notified Body No. 1023